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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/721,168 | 11/22/2000 | R. Terry Dunlay | 97,022-G1 | 5283 |

7590 11/03/2004
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EXAMINER

CHEU, CHANGHWA J

| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,168

Applicant(s)

DUNLAY ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15,21-25 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15,21-25 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 7/7/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-12, 16-20, 26-27 are cancelled.
2. Currently, claims 13-15, 21-25 and 28-31 are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

2. Claims 13-15, 21-25 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for analyzing distribution between nucleus and cytoplasm, does not reasonably provide enablement for cytoplasm and membrane. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant invention directs to a method for analyzing distribution of a protein of interest between cell membrane and cell cytoplasm. Applicants disclose using ratio/or difference between the cytoplasm and membrane of a protein of interests as in indication of the cellular distribution of the said protein.

However, the current invention merely outlines the measuring of intracellular trafficking from cytoplasm to the nucleus which is the also the core content of its parent application, now patented as US 6620591. Particularly, Figures 5, 6, 7, 8, 9, illustrate the measurements of a cell's fluorescent molecules within the local cytoplasmic region of the cell and the translocation of fluorescent molecules from the cytoplasm to the nucleus (emphasis added; See page 12, line 21-26). Most importantly, the only two working examples, i.e. example 1 and 2, do not provide any guidance as to the measurement of distribution from cell membrane to the cytoplasm (See example 1 and 2, from page 15-16).

In Example 1, applicant measures the transcription factor by labeling the *nuclei*, and measuring the *nuclei* region and cytoplasmic region (See page 15, line 10-25; Figure 6-8). The results are shown in Figure 6 and 8, and applicant clearly indicates the data refer to the cytoplasmic intensity and the *nuclear* intensity (See page 17, line 1-15). In Example 2, applicant discloses using antibody specific for cell surface marker (myosin and actin) and DNA label Hoechst (See page 18, line 1-15). Note, DNA marker Hoechst is for localization of nuclear proteins trafficking. There is no cytoplasm fluorescent reporter molecule that report on cell membrane is taught in example 2. In light of the instruction outlined in example 2, the set of data acquired in the instant invention merely demonstrate the trafficking between cell surfaces, i.e. membrane, and nuclear, not between cytoplasm and the membrane. Given the fact that both "nuclei" and "cytoplasm" are patentably distinct in terms of the morphology, structures and functions. With limited information, it would be a leap of faith to extrapolate the information from nuclei-cytoplasm to cytoplasm-membrane. Applicant's invention is entitled to encompass analyzing distribution of a protein of interest between cell cytoplasm and the nucleus.

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Response to Applicant's Arguments

1. Applicant's arguments with respect to claims 13-15, 21-25 and 28-31 have been considered but are moot in view of the new ground(s) of rejection.
2. Accordingly, the allowable subject matters indicated in the previous Office Action are thus withdrawn pursuant to the new ground of rejections set forth in this Office Action.

Conclusion

3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



October 6, 2004


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/14/04